MAIL STOP APPEAL BRIEF-PATENTS 3003-1170

IN THE U.S. PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

Jeremy MARSHALL et al.

Conf. 1342

Application No. 10/563,318

Group 3767

Filed January 4, 2006

Examiner M. Anderson

AUTOMATIC PEN-TYPE INJECTOR

APPEAL BRIEF

MAY IT PLEASE YOUR HONORS:

1. Real Party in Interest

The real party in interest in this appeal is the Assignee, Owen Mumford Limited of Oxfordshire, England.

2. Related Appeals and Interferences

None.

3. Status of the Claims

Claims 7-13 are pending from whose final rejection the present appeal is taken. Claims 1-6 were previously canceled.

4. Status of Amendments

An amendment after final was filed on January 2, 2008 that made changes to the specification. The Advisory Action of January 30, 2008 indicated that the amendment would be entered

for purposes of Appeal. 05/01/2008 ETECLE1 00000017 10563318

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5. Summary of Claimed Subject Matter

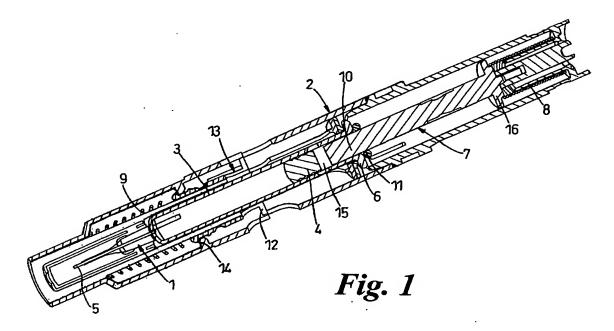
With reference to page 1, lines 3-10 of the specification, the invention relates to an automatic injection device which when operated causes the needle of a syringe to be moved forwardly so that the needle projects from a protective housing prior to actuation of the syringe to expel a dose of liquid through the needle.

Claim 7 is the only independent claim.

As recited in claim 7 and illustrated by way of example in Figure 1, reproduced below, the injection device causes a dose of liquid to be ejected from a needle 5 at one end of a syringe 1 located within a housing 2 of the device. See specification page 1, lines 11-13. The syringe 1 is movable by a plunger 7, upon release of an actuating bias member 8 at one end of the housing 2, to move the syringe 1, from a first position (as seen in Figure 1) wherein the needle 5 is shrouded by the housing 2, to a second position (as seen in Figure 2) wherein the needle 5 projects from the other end of the housing 2. See page 1, lines 13-17

The plunger 7 has a free end 10 positioned within the other end of a container 3 of the syringe 1 and carrying a surrounding and gripping flexible O-ring 11 which rests against an enlarged head 6 of the other end of the syringe container 3, such that a primary movement of the plunger 7, under the bias of the actuating bias member 8, will transmit a frictional force to the 0-ring with the result that the syringe container 3 is moved by

and with the O-ring linearly from said first to said second position. See page 1, lines 17-22. Whereupon arresting of further movement of the syringe container 3 results in the frictional grip between the plunger 7 and the O-ring 11 being overcome, thus enabling the plunger 7 to move by a secondary movement relatively to the O-ring 11, into the syringe container 3, into contact with and to act upon a plug 4 to compress the liquid within the syringe 1 and cause expression of the liquid through the syringe needle 5. See page 1, line 23 to page 2, line 3.



As set forth on page 2, lines 4-11, the recited device produces a two-step movement of the plunger. Firstly, together with the syringe through the medium of the O-ring, and secondly, within the syringe container to force the plug forward when the frictional force between the plunger and the O-ring is relieved and the plunger slides forward through the O-ring.

6. Ground of Rejection to be Reviewed on Appeal

The sole issue on appeal is whether the rejection of claims 7-13 under 35 USC \$102(b) as anticipated by GABRIEL et al. was proper.

7. Arguments

The final rejection argues (Response to Arguments on Page 4) that

"With regard to linear movement of the O-ring, GABRIEL et al. discloses the O-ring frictional slip clutch system (column 8, line 64 to column 9, line 5 and claim 10) and includes the use of variations on the concept. Besides the presents (sic) of rotational friction also implies the presents (sic) of linear friction".

However, this position is believed to be clearly untenable for at least the following reasons.

First, based on what is disclosed in GABRIEL, this reference does not meet the present claims. Although the above-noted passage refers to an O-ring 98, nevertheless, O-ring 98 is not an O-ring which rests against an enlarged head of an end of a syringe container, and that movement of a plunger results in the syringe container is moved by and with the O-ring linearly from a first to a second position as recited.

Rather, O-ring 98 remains axially (linearly) stationary between first ridged sleeve 70 and second ridged sleeve 92 at all times. As disclosed on column 8, line 64 to column 9, line 16, O-ring 98 permits adjusting member 65 to rotate in the direction

of arrow 99 in Figure 6 so that the plunger lengthening mechanism 77 increases the plunger length. That is, rotation of the adjusting member 65 rotates first flange member 70, O-ring 98 and second flange member 92 with respect to each other so that the second flange member 92 rotates the spring 95 attached thereto to uni-directionally drive the plunger-lengthening mechanism 77. See column 8, lines 38-62.

However, as seen by comparing Figures 1 and 2 of GABRIEL, such rotation and lengthening of mechanism 77 do not axially move the O-ring with the syringe container. Rather, only the plunger 18 is lengthened.

The only axial movement of the O-ring in GABRIEL is upon compression/decompression of the O-ring. As disclosed on column 12, lines 11-25 of GABRIEL, compression of O-ring 98 between first and second sleeves 70, 92 enables the rotation of adjusting member 65 to lengthen plunger lengthening mechanism 77, but when the O-ring is not compressed, slippage occurs (thus, the reason why GABRIEL refers to O-ring 98 as a slip clutch), and the sleeves 70, 92 slip with respect to each other. Such compression/decompression does not meet the recited movement of the plunger resulting in the syringe container is moved by and with the O-ring linearly from a first position (wherein the needle is shrouded by the housing) to a second position (wherein the needle projects from the other end of the housing).

Moreover, as the O-ring 98 is between sleeves 70, 92, O-ring 98 does not rest against a head of the syringe (noted as element 12 in the final rejection).

Second, GABRIEL fails to disclose that the plunger transmits a frictional force to the 0-ring resulting in the syringe container is moved by and with the 0-ring as recited.

Returning to the O-ring 98 in GABRIEL, it is seen that this element is part of the dose setting mechanism and plays no active part in controlling the forward movement of the syringe container and the subsequent expulsion of the dose.

Rather, as set forth above, the function of the O-ring 98 is to act as a slip coupling or slip clutch to permit rotary movement to be transmitted between the flange 74 of a flanged sleeve 70 and the flange 94 of a sleeve 92 (see Figures 2 and 4 and column 8, lines 63 to column 9, line 35). The flanged sleeve 70 is secured to the adjustment member 65 by a lock screw (column 7, lines 38 to 46 view O-ring 98) and so rotation of the adjustment member 65 is transmitted to the sleeve 92 unless the plunger lengthening mechanism 77 to which sleeve 92 itself transmits rotation is blocked against rotation (because the plunger 18 has reached its full extension).

In this instance, the O-ring 98 instead of transmitting rotation between sleeves 70 and 92 will slip (see column 9, lines 30 to 35). In other words, the element 98 simply provides a rotary clutch with a torque-limiting feature. There is no

disclosure of there being a frictional force applied between the O-ring 98 and the plunger lengthening mechanism 77 which extends therethrough. To suggest that O-ring 98 would exert a frictional engagement of element 77 is pure conjecture as GABRIEL makes no mention at all of any frictional engagement between O-ring 98 and element 77. O-ring 98 of GABRIEL does not serve any active purpose in the linear interaction between the plunger and syringe bung or plug.

In view of the above, it is apparent that it is incorrect to say that the presence of rotational friction in GABRIEL implies the presence of linear friction. Rather, these friction forces are separate and distinct, resulting in different outcomes. GABRIEL is concerned with an O-ring providing frictional engagement between two rotating sleeves whereas claim 7 is concerned with providing frictional engagement between the plunger and the O-ring itself to produce linear movement of the O-ring until a certain point at which time the plunger then moves through the O-ring.

Accordingly, GABRIEL fails to disclose at least:

- 1) an O-ring which rests against an enlarged head of the other end of the syringed container;
- 2) a primary movement of the plunger transmitting a frictional force to the O-ring;
- 3) the syringe container being moved by and with the Oring linearly;

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4) arresting of further movement of the syringe resulting in the frictional grip between the plunger and the O-ring being overcome; and

5) primary and secondary movements of the plunger whereby in the primary mode the plunger, O-ring and syringe container all move as one whereas in the secondary mode the plunger moves relative to the O-ring (and also the syringe container).

Conclusion

For these reasons, Appellants respectfully urge that the rejection on appeal should not be maintained, and respectfully request that this rejection be reversed.

Respectfully submitted,

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April 30, 2008

8. Claims Appendix:

- 7. An injection device for causing a dose of liquid to be ejected from the needle at one end of a syringe located within a housing of the device, the syringe being movable by a plunger, upon release of an actuating bias member at one end of the housing, to move the syringe, from a first position wherein the needle is shrouded by the housing, to a second position wherein the needle projects from the other end of the housing, the plunger having its free end positioned within the other end of a container of the syringe and carrying a surrounding and gripping flexible O-ring which rests against an enlarged head of the other end of the syringe container, such that a primary movement of the plunger, under the bias of the actuating bias member, will transmit a frictional force to the 0-ring with the result that the syringe container is moved by and with the O-ring linearly from said first to said second position, whereupon arresting of further movement of the syringe container results in the frictional grip between the plunger and the O-ring being overcome, thus enabling the plunger to move by a secondary movement relatively to the O-ring, into the syringe container, into contact with and to act upon a plug to compress the liquid within the syringe and cause expression of the liquid through the syringe needle.
- 8. An injection device as claimed in claim 7, wherein a pressure maintaining bias member is positioned between a head

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of the plunger and the O-ring to enable pressure to be maintained by the O-ring onto the head of the syringe container during the secondary movement of the plunger.

- 9. An injection device as claimed in claim 7, including a return bias member acting between the syringe housing and the other end of the syringe container to hold the syringe retracted within the housing until the actuating bias member is released.
- 10. An injection device as claimed in claim 7, wherein one or more of the bias members provided within the housing is in the form of a coil spring.
- 11. An injection device as claimed in claim 8, including a return bias member acting between the syringe housing and the other end of the syringe container to hold the syringe retracted within the housing until the actuating bias member is released.
- 12. An injection device as claimed in claim 8, wherein one or more of the bias members provided within the housing is in the form of a coil spring.
- 13. An injection device as claimed in claim 9, wherein one or more of the bias members provided within the housing is in the form of a coil spring.

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9. Evidence Appendix

None.

10. Related Proceedings Appendix

None.